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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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DIANE D. KEYERS  
ECKERT SEAMANS OHERIN & MELLOTT LLC  
300 GRAY STREET  
44TH FLOOR  
PITTSBURGH PA 15219

HM12/0712

EXAMINER

WABE.T

ART UNIT

PAPER NUMBER

1515

DATE MAILED:

07/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/538,829

Applicant(s)

MODI, PANKAJ

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-34, 36-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26,27 and 37 is/are rejected.
- 7) ☒ Claim(s) 28,30-34 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of amendment filed 4-27-01 is acknowledged. Claim 26 has been amended as requested and claim 35 has been canceled. Claims 26-34, and 36-37 are pending.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 26-27 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Manning et al (5,770,559; hereafter '559).

3. '559 discloses pulmonary aerosols comprising insulin micelles that are administered with a metered dose inhaler (C 10, L34-44; Examples 4 and 13). '559 does not specifically state buccal administration of the disclosed compositions, however it is submitted that inhalation of the composition of '559 through the mouth would inherently result in buccal administration of the composition.

#### ***Response to Arguments***

4. Applicant's arguments filed 4-27-01 have been fully considered but they are not persuasive. Applicant argues that '559 does not anticipate the instant claims as the instant claims require spraying an effective amount of insulin to the buccal mucosa and resisting substantial inhalation of insulin. However, it is submitted that inhalation of the

insulin depends upon the patient and applicant has not shown that patients of '559 do not resist inhalation. The reference meets the limitations of the instant claims because the process of the instant claims and the process of administration of the effective dose of insulin in '559 both involve oral administration of insulin.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 26-27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al (5,770,559; hereafter '559).

'559 teaches pulmonary aerosols comprising insulin micelles that are administered with a metered dose inhaler (C 10, L34-44; Examples 4 and 13). '559 does not specifically state buccal administration of the disclosed compositions, however it is submitted that inhalation of the composition of '559 through the mouth would inherently result in buccal administration of the composition.

7. Claims 26-27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radhakrishnan (5,049,389; hereafter '389).

'389 teaches pulmonary administration of insulin containing micelles by means of a metered dose inhaler. The instant claims require buccal administration of the composition. '389 does not specifically state that the is administered buccally, however

it is submitted that inhalation of the composition of '389 through the mouth would inherently result in buccal administration of the composition.

### ***Response to Arguments***

8. Applicant's arguments filed 4-27-01 have been fully considered but they are not persuasive. Applicant's arguments regarding the '559 and '389 references with respect to the 35 U.S.C. 103(a) rejection are similar to those under 35 U.S.C. 102(e); the instant claims require spraying an effective amount of insulin to the buccal mucosa and resisting substantial inhalation of insulin and applicant submits that neither '559 nor '389 teach these limitations. However, it is submitted that inhalation of the insulin depends upon the patient and applicant has not shown that patients of '559 or '389 do not resist inhalation. The references meet the limitations of the instant claims because the process of the instant claims and the process of administration of the effective dose of insulin in '559 and '389 both involve oral administration of insulin.

### ***Allowable Subject Matter***

9. Claims 28, 30-34, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-35 of copending Application No. 09/386,285. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim methods of buccal administration of micelles comprising insulin by means of a metered dose inhaler.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

tw  
July 9, 2001